

Application No.: 10/800,162
DO NOT ENTER

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/Catherine Witczak/ (03/05/2009)

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AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions, and listings of claims in the application:

Claim 1 (withdrawn): A biodegradable implant for treating sinusitis comprising a sustained release therapeutic agent dispersed within a biodegradable matrix, wherein the biodegradable implant has at least one characteristic that substantially prevents clearance of the implant from a sinus during a treatment period after delivery of the implant into the sinus.

Claim 2 (withdrawn): The biodegradable implant of claim 1 wherein the at least one characteristic is size of the implant.

Claim 3 (withdrawn): The biodegradable implant of claim 1 wherein the at least one characteristic is shape of the implant.

Claim 4 (withdrawn): The biodegradable implant of claim 1 wherein the at least one characteristic is density of the implant.

Claim 5 (withdrawn): The biodegradable implant of claim 1 wherein the at least one characteristic is viscosity of the implant.

Claim 6 (withdrawn): The biodegradable implant of claim 1 wherein the at least one characteristic is mucoadhesiveness of the implant.

Claim 7 (withdrawn): The biodegradable implant of claim 1 wherein the sustained release therapeutic agent is selected from the group consisting of anti-infective agents, anti-inflammatory agents, and combinations thereof.

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Claim 8 (withdrawn): The biodegradable implant of claim 1 wherein the sustained released therapeutic agent comprises an anti-infective agent.

Claim 9 (withdrawn): The biodegradable implant of claim 8 wherein the anti-infective agent is selected from the group consisting of antibacterial agents, antifungal agents, antiviral agents, and antiseptics.

Claim 10 (withdrawn): The biodegradable implant of claim 8 wherein the anti-infective agent comprises an antibacterial agent.

Claim 11 (withdrawn): The biodegradable implant of claim 10 wherein the antibacterial agent is selected from the group consisting of aminoglycosides, amphenicols, ansamycins, β -lactams, lincosamides, macrolides, nitrofurans, quinolones, sulfonamides, sulfones, tetracyclines, and any of their derivatives.

Claim 12 (withdrawn): The biodegradable implant of claim 10 wherein the antibacterial agent comprises a β -lactam.

Claim 13 (withdrawn): The biodegradable implant of claim 12 wherein the β -lactam comprises a penicillin.

Claim 14 (withdrawn): The biodegradable implant of claim 13 wherein the penicillin comprises amoxicillin.

Claim 15 (withdrawn): The biodegradable implant of claim 1 wherein the sustained release therapeutic agent is an anti-inflammatory agent.

Claim 16 (withdrawn): The biodegradable implant of claim 15 wherein the anti-inflammatory agent is a nonsteroidal anti-inflammatory agent or a steroidal anti-inflammatory agent.

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Claim 17 (withdrawn): The biodegradable implant of claim 1 wherein the sustained release therapeutic agent comprises a steroidal anti-inflammatory agent.

Claim 18 (withdrawn): The biodegradable implant of claim 17 wherein the steroidal anti-inflammatory agent is selected from the group consisting of 21-acetoxypregnenolone, alclometasone, algestone, amcinonide, beclomethasone, betamethasone, budesonide, chloroprednisone, clobetasol, clobetasone, clocortolone, cloprednol, corticosterone, cortisone, cortivazol, deflazacort, desonide, desoximetasone, dexamethasone, diflorasone, diflucortolone, difluprednate, enoxolone, fluazacort, flucoronide, flumethasone, flunisolide, fluocinolone acetate, fluocinonide, fluocortin butyl, fluocortolone, fluorometholone, fluprednolone acetate, fluprednidene acetate, fluprednisolone, flurandrenolide, fluticasone propionate, formocortol, halcinonide, halobetasol propionate, halometasone, halopredone acetate, hydrocortamate, hydrocortisone, loteprednol etabonate, mazipredone, medrysone, meprednisone, methylprednisolone, mometasone furoate, paramethasone, prednicarbate, prednisolone, prednisolone 25-diethylamino-acetate, prednisolone sodium phosphate, prednisone, prednival, prednylidene, rimexolone, tixocortol, triamcinolone, triamcinolone acetate, triamcinolone benetonide, triamcinolone hexacetate, and any of their derivatives.

Claim 19 (withdrawn): The biodegradable implant of claim 18 wherein the steroidal anti-inflammatory agent comprises budesonide.

Claim 20 (withdrawn): The biodegradable implant of claim 18 wherein the steroidal anti-inflammatory agent comprises mometasone furoate.

Claim 21 (withdrawn): The biodegradable implant of claim 18 wherein the steroidal anti-inflammatory agent comprises beclomethasone.

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Claim 22 (withdrawn): The biodegradable implant of claim 1 wherein the biodegradable matrix is a biodegradable polymer matrix.

Claim 23 (withdrawn): The biodegradable implant of claim 1 wherein the biodegradable matrix comprises a mucoadhesive polymer.

Claim 24 (withdrawn): The biodegradable implant of claim 23 wherein the mucoadhesive polymer is selected from the group consisting of homopolymers of acrylic acid monomers and their pharmaceutically acceptable salts; copolymers of acrylic acid and methacrylic acid, styrene, or vinyl ethers; polyhydroxyethyl acrylate; polyhydroxyethyl methacrylate; polyvinyl alcohol; polyvinyl pyrrolidone; methyl cellulose; ethyl cellulose; hydroxyethyl cellulose; hydroxypropyl cellulose; hydroxypropylmethyl cellulose; carboxymethyl cellulose; alginic acid; sodium alginate; tragacanth gum; collagen; gelatin; and any combination thereof.

Claim 25 (withdrawn): The biodegradable implant of claim 1 wherein the biodegradable matrix comprises poly(lactic-co-glycolic)acid (PLGA) copolymer.

Claim 26 (withdrawn): The biodegradable implant of claim 25 wherein the sustained release therapeutic agent comprises amoxicillin.

Claim 27 (withdrawn): The biodegradable implant of claim 25 wherein the sustained release therapeutic agent comprises budesonide.

Claim 28 (withdrawn): The biodegradable implant of claim 25 wherein the sustained release therapeutic agent comprises mometasone furoate.

Claim 29 (withdrawn): The biodegradable implant of claim 25 wherein the sustained release therapeutic agent comprises beclomethasone.

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Claim 30 (withdrawn): The biodegradable implant of claim 1 wherein the biodegradable matrix comprises a poly(ortho ester).

Claim 31 (withdrawn): The biodegradable implant of claim 1 wherein the treatment period is about one week to about three months.

Claim 32 (withdrawn): The biodegradable implant of claim 1 wherein the treatment period is about two weeks to about 4 weeks.

Claim 33 (withdrawn): The biodegradable implant of claim 1 wherein the implant is of a form selected from the group consisting of rods, pellets, beads, strips, and microparticles.

Claim 34 (withdrawn): The biodegradable implant of claim 1 wherein the implant is a microparticle.

Claim 35 (withdrawn): The biodegradable implant of claim 34 in a pharmaceutically acceptable carrier.

Claim 36 (withdrawn): The biodegradable implant of claim 35 wherein the pharmaceutically acceptable carrier is a semi-solid gel.

Claim 37 (withdrawn): The biodegradable implant of claim 1 wherein the implant further comprises a series of predetermined fracture lines such that after delivery into the sinus, the implant fractures into a plurality of segments.

Claim 38 (withdrawn): The biodegradable implant of claim 1 wherein the sinus is a maxillary sinus, a frontal sinus, an ethmoid sinus, or a sphenoidal sinus.

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Claim 39 (withdrawn): The biodegradable implant of claim 1 wherein the sinus is the maxillary sinus.

Claim 40 (withdrawn): A biodegradable implant for reducing inflammation from a sinus procedure comprising a sustained release therapeutic agent dispersed within a biodegradable matrix, wherein the biodegradable implant has at least one characteristic that substantially prevents clearance of the implant from a sinus during a treatment period after delivery of the implant into the sinus.

Claim 41 (withdrawn): The biodegradable implant of claim 40 wherein the sinus procedure is a sinus drainage procedure.

Claim 42 (withdrawn): The biodegradable implant of claim 40 wherein the sinus procedure enlarges a narrowed sinus ostium.

Claim 43 (withdrawn): The biodegradable implant of claim 40 wherein the sinus procedure is antral puncture and washout.

Claim 44 (withdrawn): The biodegradable implant of claim 40 wherein the sinus procedure is intranasal antrostomy.

Claim 45 (withdrawn): The biodegradable implant of claim 40 wherein the biodegradable matrix is a biodegradable polymer matrix.

Claim 46 (withdrawn): The biodegradable implant of claim 40 wherein the sustained release therapeutic agent is mometasone furoate.

Claim 47 (withdrawn): A system for treating sinusitis comprising:

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a) an implant delivery device, the implant delivery device comprising a conduit having a lumen, a distal portion, a side wall, a tip, and an opening in said distal portion; and a pusher within the lumen; and

b) one or more biodegradable implants in the lumen of the implant delivery device, the one or more biodegradable implants comprising a sustained release therapeutic agent dispersed within a biodegradable matrix and having at least one characteristic that substantially prevents clearance of the one or more implants from a sinus during a treatment period after delivery of the one or more implants into the sinus,

wherein the one or more implants are delivered into the sinus by distally advancing the pusher to slidably engage the one or more implants and move the one or more implants through the opening in the distal portion of the conduit.

Claim 48 (withdrawn): The system of claim 47 wherein the biodegradable matrix is a biodegradable polymer matrix.

Claim 49 (withdrawn): The system of claim 47 wherein the distal portion of the conduit is angulated.

Claim 50 (withdrawn): The system of claim 47 wherein the conduit is preloaded with a single implant.

Claim 51 (withdrawn): The system of claim 47 wherein the conduit is preloaded with a plurality of implants.

Claim 52 (withdrawn): The system of claim 47 further comprising a tool for visualizing the sinus ostium or sinus wall.

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Claim 53 (withdrawn): The system of claim 52 wherein the tool is an endoscope.

Claim 54 (withdrawn): The system of claim 52 wherein the tool is a computed tomography scanner.

Claim 55 (withdrawn): The system of claim 47 wherein the conduit is a needle.

Claim 56 (withdrawn): The system of claim 47 wherein the conduit is a catheter.

Claim 57 (withdrawn): The system of claim 47 wherein the conduit is malleable.

Claim 58 (currently amended): A method for delivering a biodegradable implant into a paranasal sinus cavity comprising:

a) loading one or more biodegradable implants into a conduit having a lumen, a distal portion, a side wall, a tip, and an opening in the distal portion;

b) creating access to the paranasal sinus cavity with the loaded conduit; and

c) delivering the one or more biodegradable implants through the opening in the distal portion of the conduit into the paranasal sinus cavity,

wherein the one or more biodegradable implants comprise a therapeutic amount of an active agent for the treatment of sinusitis.

Claim 59 (previously presented): The method of claim 58 wherein creating access comprises advancing the conduit through a paranasal sinus ostium.

Claim 60 (withdrawn): The method of claim 58 wherein creating access comprises advancing the conduit through a paranasal sinus wall.

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Claim 61 (previously presented): The method of claim 58 wherein delivering the one or more biodegradable implants comprises delivering the one or more biodegradable implants with a pusher.

Claim 62 (withdrawn): The method of claim 58 wherein delivering the one or more biodegradable implants comprises contacting the one or more biodegradable implants with a pressurized gas.

Claim 63 (original): The method of claim 58 wherein the distal portion of the conduit is angulated.

Claim 64 (original): The method of claim 58 wherein the conduit is sharp-tipped.

Claim 65 (withdrawn): The method of claim 58 wherein the distal opening is located in the side wall of the conduit.

Claim 66 (previously presented): The method of claim 58 wherein the distal opening is located at the tip of the conduit.

Claim 67 (original): The method of claim 58 wherein the biodegradable implant is a biodegradable polymeric implant.

Claim 68 (currently amended): A method for delivering a biodegradable implant into a paranasal sinus cavity comprising:

a) loading one or more biodegradable implants into a conduit having a lumen, a distal portion, a side wall, a tip, and an opening in the distal portion;

b) creating access to the paranasal sinus cavity with the loaded conduit; and

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c) delivering the one or more biodegradable implants through the opening in the distal portion of the conduit into the paranasal sinus cavity,

wherein the one or more biodegradable implants comprise a therapeutic amount of an active agent for the reduction of inflammation.

Claim 69 (previously presented): The method of claim 68 wherein creating access comprises advancing the conduit through a paranasal sinus ostium.

Claim 70 (withdrawn): The method of claim 68 wherein creating access comprises advancing the conduit through a sinus wall.

Claim 71 (original): The method of claim 68 wherein the biodegradable implant is a biodegradable polymeric implant.

Claim 72 (original): The implant of claim 68 wherein the active agent comprises mometasone furoate.